美科 Meike ®

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Section 5 510(k) Summary

5.1 Submitter Information

• Company: Mianyang Meike Electronic Equipment Co.,Ltd.

• Address: No.238, Middle Section of Chuanye Road, Kechuang-yuan Zone,
Mianyang City, Sichuan Province, South-West of China

• Phone: 086-816-6355076

• Fax: 086-816-6355070

• E-mail: whkltzlb@163.com

• Contact: Wenjun Zhao, General Manager

• Date: November 20, 2012

5.2 Device Information

• Trade/Proprietary Name: Palm Bladder Scanner-PBSV 4.1

• Common Name: Diagnostic Ultrasound System with Accessories

• Classification Name(s): Device Class: 2

Review Panel: Radiology

Ultrasonic Pulsed Echo Imaging System

• Regulation Number 892.1560

• Product Code: IYO

Diagnostic Ultrasound Transducer

• Regulation Number 892.1570

• Product Code: ITX

• Predicate Device: Verathon BladderScan® BVI 9400 Ultrasound System (K071217)

• Device Description

Palm bladder scanner is a medical device with high performance combined with modern B-mode ultrasound technology and computer technology. The device consists of host and probe, it can

speedily complete the detection of bladder area through scan of probe connected with the device, and transmit B ultrasound echo signal detected to embedded computer system after processing before computer identifies the edge of image and volume calculation, realizes the measurement of bladder volume, displays and prints out the relative information through LED/built-in printer.

• Intended Use:

New Device: PBSV4.1 bladder scanner is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

5.3 Comparison of Required Technology Characteristics:

Item		Subject Device PBSV4.1	Predicate Device BVI 9400 (K071217)
Mode of Operation		B	B
Transducer Characteristics	Type	2.6MHz Mechanical Sector Scan	3.0MHz and 1.74 MHz Mechanical Sector Scan
	Time from 3D Scan Initiation to Result Display	4 seconds	<3 seconds
	Penetration Depth	≥140mm	≥150mm
Range of Measurement		0-999ml	Adult: 0-999ml Small Child: 0-200ml
Accuracy		• ± 25% (60ml ≤ volume ≤150ml) • ± 15% (150ml ≤ volume ≤999ml)	±15%, ±15ml

Power Supply		7.4v Li Ion Rechargeable	11.1v Li Ion Rechargeable
Screen Display		Color LCD	Color LCD
Operation Condition		•Temperature: +5℃~+40℃ • Humidity Rate: ≤70% •Atmospheric Pressure: 700hPa~1060hPa	•Temperature: +10℃~+40℃ • Humidity Rate: 30%~75% •Atmospheric Pressure: 700hPa~1060hPa
Acoustic Output	Maximum MI	0.89	0.95
	Maximum TIS	0.98	4.0
Target Population		Adult and Children	Adult and Children
Anatomical Sites		Abdomen	Abdomen

The PBSV4.1 incorporates the same fundamental technologies, such as the mode of operation, transducer type, anatomical sites and range of measurement, with the predicate device. Then though the subject device and the predicate device differ in the specific transducer specification and acoustic output parameters, such differences will not influence the major function of the subject device and cause safety and effectiveness concerns. Besides, the subject device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued on September 9, 2008 and its acoustic output are within the Pre-amendment limit.

5.4 Discussion of Tests Performed

• Clinical Tests:

No clinical tests were included.

• Non-clinical Tests:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. AAMI/ANSI/ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity. (Biocompatibility)

b. AAMI/ANSI/ISO 10993-10:2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization. (Biocompatibility)

c. AAMI/ANSI/IEC 60601-1-2:2007, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-collateral standard: Electromagnetic compatibility-Requirements and tests (Edition 3). (General)

d. IEC 62359 Edition 2.0 2010-10-10,Ultrasonics- Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields. (Radiology)

e. IEC 60601-2-37 Edition 2.0 2007-08, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (Radiology)

5.5 Conclusion

From the above comparison table and relative tests that have been conducted, it is reasonable to conclude that the subject device – PBS V 4.1 is as safe and effective as the predicate device – BVI 9400, that they are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Mianyang Meike Electronic Equipment Co., Ltd.
% Ms. Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room 404, Bldg 7, Jinhuichang Homeland, Liuhongqiao Road
Wenzhou City, Zhejiang Province, 325000
CHINA

Re: K130229
Trade/Device Name: PBSV4.1 Palm Bladder Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Codes: IYO, ITX
Dated: January 10, 2013
Received: February 12, 2013

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the PBSV4.1 Palm Bladder Scanner, as described in your premarket notification:

Transducer Model Number

SD2-001

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Meike ®

Mianyang Meike Electronic Equipment Co., Ltd.

Section 4 Indications for Use Statement

510(k) Number (if known): ____New Submission_____
Device Name: _____PBSV4.1 Palm Bladder Scanner_____

Indications for Use:

- Abdomen, B-Mode, per Indications for Use Ultrasound Form
- PBSV4.1 bladder scanner is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively.

Contradictions:

- PBSV4.1 is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

Prescription Use		Over-The-Counter Use _____
___X___	AND/OR	(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH. Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k) K130229

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM 1

System: PBSV 4.1 Palm Bladder Scanner

Transducer: 2.6MHz High-Frequency Focused Transducer – SD2-001

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							

	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other(Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other(Bladder)	**P**						

N=new indication; P=previously cleared by FDA (K071217);

E=added under this appendix

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM 2

System: PBSV4.1 Palm Bladder Scanner

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal							
	Abdominal	**P**						
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal							

	(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other(Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other							

N=new indication; P=previously cleared by FDA (K071217);

E=added under this appendix

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
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